

**REMARKS****Status:**

This document is submitted as a full and complete response to the Office Action dated March 22, 2006. Upon entry of the amendment claims 1-9 and 11-26 will be pending with none having been allowed. Claims 1, 7, 8, and 18 are independent claims. Claim 10 has been canceled for reasons not related to the rejections in the Office Action. Further examination of the claims is hereby requested in light of the amendments to the claims and the following remarks. No new matter has been added.

**1. Rejection under 35 U.S.C. §101.** In the Office Action dated March 22, 2006, the Patent Office rejected claims 1-10 under 35 U.S.C. §101, stating that “applicant positively recites parts of the ear piece in the ear and connections thereto. ... [A]pplicant may not recite any part of the human body as part of their invention.”

This rejection is respectfully traversed. Although claim 1 has been amended and it is believed that this rejection does not apply to amended claim 1, the limitations of the original claim 1, except for the requirement that the tympanic membrane be “intact”, have been incorporated into original dependent claims 7 and 8, which have now been made independent, and therefore it is appropriate to discuss why this rejection is inappropriate for the original claim 1 and, therefore, inappropriate to the amended claims 7 and 8. Original Claim 1 began “A magnetic field modulation system for a cochlear implant surgically implantable into a human ear”, thus setting forth the environment in which the claimed invention is to be used; and then adds “the magnetic field modulation system comprising”. Thus, it is clear that the claimed invention in original claim 1 comprises “a transmitting coil ...”, “a receiving coil ...”, and “means connected to said receiving coil ...”. The remaining language associated with each element either specifies a requirement for that element and/or specifies how the element is to be connected and/or positioned with respect to the environment – such as the human ear or some man-made components: “an audio signal processor, switching amplifier and at least one microphone”. Thus, neither the human ear nor the components thereof are recited as part of the invention.

Applicant refers the Patent Office to 35 U.S.C. § 112, second paragraph, which requires that the claims particularly point out and distinctly claim the subject matter which the applicant regards as his invention. Removal of references to the environment (the human ear) could result in uncertainty as to how the claimed invention achieves its usefulness.

Therefore, withdrawal of the 35 U.S.C. §101 rejection of claims 7 and 8, as amended, is respectfully requested.

**2. Rejection under 35 U.S.C. §112.** In the Office Action dated March 22, 2006, the Patent Office rejected claims 1-10 under 35 U.S.C. §112, second paragraph, stating: "it is difficult to tell which pieces of the device applicant intends to claim since, for instance, the amplifier is recited in the preamble yet there is a positive connection to it to the transmission coil in the body of the claim."

This rejection is respectfully traversed. Although claim 1 has been amended and it is believed that this rejection does not apply to amended claim 1, the limitations of the original claim 1 have been incorporated into original dependent claims 7 and 8, which have now been made independent, and therefore it is appropriate to discuss why this rejection is inappropriate for the original claim 1 and, therefore, to the amended claims 7 and 8. As shown above, the claimed invention in original claim 1 comprises "a transmitting coil ...", "a receiving coil ...", and "means connected to said receiving coil ...". The remaining language associated with each element either specifies a requirement for that element and/or specifies how the element is to be connected and/or positioned with respect to the environment – such as the human ear or some man-made components: "an audio signal processor, switching amplifier and at least one microphone". Removal of the references to the other man-made components could result in the elements of the claimed invention being set forth in a vacuum, with no reference to their environment or use.

Therefore, withdrawal of the 35 U.S.C. §112, second paragraph rejection of claims 7 and 8, as amended, is respectfully requested.

**3. Rejection under 35 U.S.C. §103.** In the Office Action dated March 22, 2006, the Patent Office rejected claims 1-6 and 9-10 under 35 U.S.C. §103(a) as being unpatentable over Killion USPN 4,689,819 in view of von Ilberg USPN 6,231,604 or Michelson USPN 3,751,605. The

Patent Office stated that while Killion teaches a class D hearing aid amplifier which outputs a mechanical acoustic wave sound through a matched coil, to have converted the output to a cochlea electrical stimulator using communicating coil antennas by substituting it into the amplifier members of Von Ilberg or Michelson would have been obvious. The Patent Office also stated that using capacitors for demodulation filter was well known.

Claims 7 and 8. The Patent Office did not state any reason for rejection of claims 7 and 8. 37 CFR §1.104 (a)(1), entitled "Examiner's action" specifies: "The examination shall be complete with respect ... to the patentability of the invention as claimed." 37 CFR §1.104 (b), entitled "Completeness of examiner's action" specifies: "The examiner's action will be complete as to all matters ..." 37 CFR §1.104 (c)(2), entitled "Rejection of claims" specifies: "In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. ... The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified." As the Patent Office did not give any particulars regarding the rejection of claims 7 and 8, and as the cited art does not appear to discuss the construction limitations of claims 7 and 8, it is believed that claims 7 and 8 are patentable. Claims 7 and 8 both previously depended from original independent claim 1. Also, as discussed above, the 35 U.S.C. 101 and 112 rejections of claim 1 were improper. Accordingly, except for the requirement that the tympanic membrane be intact, the limitations of original independent claim 1 have been incorporated into claims 7 and 8, and they have both been made to be independent claims. Allowance of claims 7 and 8 is therefore respectfully requested.

Claims 1-6, 9, and 11-17. Claims 2-6, 9 and 11-17 all depend from amended claim 1. Claim 1 has been amended to claim the invention in a different manner than previously even though, as previously discussed, the 35 U.S.C. 101 and 112 rejections of claim 1 were improper.

Independent claim 1, as now amended, specifies that there is "an external portion to be inserted into the auditory canal" and "a cochlear implant portion surgically implantable into the middle ear space".

The "external portion" requires "a Class D switching amplifier ... having a switching frequency" and "a transmitting coil ... having a low inductance at the switching frequency." Killion shows a class D amplifier driving an earpiece E through a filter F. (Figs. 1-4 and 17;

Col. 6, line 67 – Col. 7, line 18.) Nicholson has a transmitting coil 75 but the driver is a UHF transmitter 74, not a Class D switching amplifier. (Fig. 7; Col. 7, lines 8-20.) Von Ilberg discloses a system which has both an acoustical output 14 and an electrical stimulation output 17, the output 17 being provided via a transmitter 15 driving a transmission coil (not numbered). Von Ilberg, however, does not disclose how the coil is driven. Thus, these three references, fairly combined without the benefit of hindsight from reading the present patent application, would only result in a von Ilberg system with an acoustical output 14 driver by Killion's Class D amplifier, and an electrical stimulation output 17 driven by Michelson's UHF transmitter. Therefore, none of Killion, von Ilberg, or Michelson, singly or in combination, suggest or disclose that a Class D switching amplifier should be used to drive a transmitting coil.

In addition, Killion specifies that the filter F is "designed to be as purely inductive as possible at the lowest component of the ultrasonic spectrum present at nodes 'd' and 'e'." Claim 1, however, requires "a transmitting coil ... having a low inductance at the switching frequency". Thus, Killion teaches that the filter F should be as inductive as possible, whereas the claim requires a low inductance. Killion therefore teaches away from the claimed invention.

The "cochlear implant portion" requires "a receiving coil electromagnetically coupled to the transmitting coil to receive the switched electrical sound signal and to provide a coupled switched electrical sound signal" and "at least one electrode connected to the receiving coil and to be inserted into the cochlea to provide substantially the coupled switched electrical sound signal to the cochlea." Killion discloses and is only concerned with an external device, not an implantable device. Von Ilberg and Michelson both disclose implantable devices, with electrodes, but Michelson (Fig. 7) requires a UHF receiver 77 and a demodulator 78 to process the signal from the receiving coil 76 before it can be delivered to the electrode 79, and von Ilberg (Fig. 1) leaves it to the reader's imagination as to exactly what processing is in the decoder stimulator 16. The term "substantially" is not to be construed as not permitting any processing or filtering of the signal from the receiving coil prior to delivery to the electrode, as dependent claim 9 adds a capacitor to the output of the receiving coil and therefore provides some processing or filtering of the signal from the receiving coil, but does exclude substantial processing, such as provided by the receiver 77 and demodulator 78 of Michelson where a UHF transmitter and receiver are used.

Independent Claim 18. New claim 18 is for the external portion of the hearing aid and requires the Class D switching amplifier and transmitting coil discussed above.

Therefore, it is respectfully submitted that claim 1, as amended, and new claim 18, are patentable over Killion, Michelson, and von Ilberg, singly and in combination. Further, as claims 2-6, 9 and 11-17 and 21-24 depend from claim 1, and claims 19 and 20 and 25-26 depend from claim 18, they are also allowable.

Claims 2 and 19. Dependent claims 2 and 19 require that "the transmitting coil operates in synchronization with the switching frequency of the switching amplifier". Synchronous operation arises from the requirement that the transmitting coil have a low inductance at the switching frequency. None of Killion, Michelson, and von Ilberg suggest or disclose synchronous operation of the transmitting coil: Killion does not have a transmitting coil, von Ilberg says nothing about the transmitting coil, and Michelson only shows that the transmitting coil is used as part of a UHF transmission scheme. Therefore, it is respectfully submitted that claims 2 and 19 are further patentable over Killion, Michelson, and von Ilberg, singly and in combination.

Claims 11 and 20. Dependent claims 11 and 20 require that "the switching amplifier has a switching frequency of approximately 2 MegaHertz." Michelson discloses a UHF transmitter, which will have a carrier frequency above 200 MegaHertz, two orders of magnitude higher; Killion discloses a Class D amplifier with a switching frequency of either 40 kHz or 100kHz (Col. 12, lines 3-9 and 33-38), over one order of magnitude lower; and von Ilberg does not discuss it at all. Therefore, it is respectfully submitted that claims 11 and 20 are further patentable over Killion, Michelson, and von Ilberg, singly and in combination.

Claim 12. Dependent claim 12 requires that "the transmitting coil and the receiving coil together act as a transformer with a low inductive impedance at the switching frequency." Neither von Ilberg nor Michelson discuss the desired inductance, and Killion indicates that the inductance should be high (Col. 7, lines 1-3), not that it should be low. Therefore, it is respectfully submitted that claim 11 is further patentable over Killion, Michelson, and von Ilberg, singly and in combination.

Claims 13-16. Dependent claims 13-16 specify the wire size and/or the number of turns of wire for the transmitting and receiving coils. None of Killion, Michelson, and von Ilberg, singly or in combination, disclose how the coils are to be made or suggest any reason for making them in the claimed manner. Therefore, it is respectfully submitted that claims 13-16 are further patentable over Killion, Michelson, and von Ilberg, singly and in combination.

Claims 21-26. Dependent claims 21-26 specify the physical (thickness and diameter) requirements of the receiving coil or the transmitting coil. None of Killion, von Ilberg, or Michelson, singly or in combination, suggest or disclose that the coils in their devices should have this size, or that such size is even possible. The small size claimed arises from the synchronous operation and the switching frequency. Therefore, it is respectfully submitted that claims 21-26 are further patentable over Killion, Michelson, and von Ilberg, singly and in combination.

#### LACK OF PRIOR IMPLEMENTATION

If the claimed subject matter were an obvious extension of the art described in Killion, von Ilberg, or Michelson, singly or in combination, it would have been implemented earlier. However, none of the cited art suggests or discloses the use of a switching amplifier as described and claimed herein. This lack of implementation supports Applicant's argument that the claims are allowable. "That an inventor has probed the strengths and weaknesses of the prior art and discovered an improvement that escaped those who came before is indicative of unobviousness, not obviousness." *Fromson v. Anitec Printing Plates, Inc.*, 45 U.S.P.Q.2d 1269 (Fed. Cir. 1997).

#### NO MOTIVATION TO COMBINE REFERENCES

When an obviousness determination is based on multiple prior art references, there must be a showing of some "teaching, suggestion, or reason" to combine the references. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997) (also noting that the "absence of such a suggestion to combine is dispositive in an obviousness determination"). Whether motivation to combine the references was shown we hold a question of fact. See *In re Dembiczak*, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("[P]articular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important

purposes . . .") (emphasis added); *Monarch Knitting*, 139 F.3d at 881-83, 886, 45 USPQ2d at 1982, 1985 (treating motivation to combine issue as part of the scope and content of the prior art and holding that genuine issues of fact existed as to whether one of ordinary skill in the art would have been motivated to combine the references in question).

Evidence of a suggestion, teaching, or motivation to combine prior art references may flow, *inter alia*, from the references themselves, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. See *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. Although a reference need not expressly teach that the disclosure contained therein should be combined with another, see *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997), <sup>6</sup> the showing of combinability, in whatever form, must nevertheless be "clear and particular." *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. \*

\* Quoted from *WINNER INTL. ROYALTY v WANG* No. 981553 - 01/27/2000 (CAFC).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention when there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 2221 U.S.P.Q. 929, 933 (C.A.F.C. 1984).

Some amendments and remarks contained in this document, or in other documents filed or to be filed with the US Patent Office in this case or related cases, may in the future be deemed, by a court of law or government agency of competent jurisdiction, to be narrowing amendments and/or related to patentability. Accordingly, the public is hereby advised that the applicant: (a) intends to relinquish only that claim coverage which is clearly, explicitly, precisely and unequivocally stated to be relinquished; (b) does not intend to relinquish any other claim coverage; (c) reserves the right to assert that any such amendments and/or remarks are not narrowing and/or are not related to patentability; and (d) intends to fully assert the full range of equivalents, under the Doctrine of Equivalents and otherwise, which are presently known or which may become known in the future, for each and every element of each and every claim, and for each and every claim.

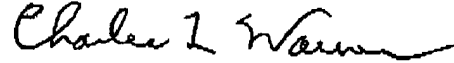
**CONCLUSION**

In view of the above it is respectfully submitted that claims 1-9, as amended, meet the requirements of 35 U.S.C. 101 and 112, second paragraph. It is further respectfully submitted that claims 1-9 and 11-26 are patentable over Killion, Michelson, and von Ilberg, singly and in combination. Accordingly, allowance of the claims is respectfully requested.

Should the Examiner have questions or suggestions which will put this application in line for allowance, he or she is requested to contact the undersigned attorney.

Respectfully submitted,

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